June 10, 2019

Via ECF

The Honorable Alvin K. Hellerstein
United States District Court
Southern District of New York
500 Pearl Street, Room 1050
New York, New York 10007

RE: *In re Novartis and Par Antitrust Litigation*, 1:18-cv-04361 (S.D.N.Y.); all actions

Dear Judge Hellerstein,

Pursuant to Rule 2.E of Your Honor's Individual Rules of Practice, all Plaintiffs[1], Novartis Pharmaceuticals Corporation ("Novartis") and Par Pharmaceutical, Inc. ("Par", and together with Novartis, "Defendants")[2] write to seek the Court's assistance in resolving a discovery dispute related to Plaintiffs' requests for production of Defendants' branded and generic Exforge sales data. The parties have reached an impasse regarding the time period for which Defendants will produce branded and generic Exforge sales data, despite the parties' efforts to reach resolution on this issue. These efforts included a meet and confer call on January 8, 2019 and the exchange of several letters and emails between February 1, 2019 and April 29, 2019.

I. Whether Defendants Should Be Compelled To Produce 2016-2017 Sales Data for Branded and Generic Exforge

Plaintiffs' Position

Plaintiffs have requested that Defendants produce branded and generic Exforge sales data through December 2017,[3] but Defendants have refused to produce any post-2015 sales data—that is, Defendants have refused to produce 2016-2017 sales data. Defendants' sales data running through 2017 is relevant to, *inter alia*, Plaintiffs' proof of damages, as Dr. Jeffrey J. Leitzinger explains in his affidavit (attached as Exhibit A). Defendants have not asserted any undue burden associated with producing this data, nor is there any burden. In addition, several non-party generic manufacturers subpoenaed by Plaintiffs have agreed to produce generic

[1] "Plaintiffs" are the Direct Purchaser Plaintiffs, the End-Payor Plaintiffs, and the Retailer Plaintiffs, including CVS Pharmacy, Inc., Walgreen Co., The Kroger Co., Rite-Aid Corporation, Rite Aid Hdqtrs. Corp., and H-E-B, L.P.

[2] Novartis AG, a defendant in the Direct Purchaser and Retailer Plaintiff actions only, is not a party to the present dispute.

[3] *See* Plaintiffs' First Set of Requests for Production of Documents to Novartis Defendants, at Requests 38-39, 42-44, 52; Plaintiffs' First Set of Requests for Production of Documents to Par Defendants, at Requests 35-36, 39-41, 49.

Exforge sales data running through 2017. The Court should compel Defendants to produce their branded and generic Exforge sales data through 2017.

A. Legal Standard

Rule 26(b)(1) recognizes that "[i]nformation is discoverable ... if it is relevant to any party's claim or defense and is proportional to the needs of the case." Rule 26 Advisory Committee Notes to 2015 Amendments. Relevance for the purposes of discovery is broader than relevance for the purposes of admissibility. *Weinberg v. Unum Life Ins. Co. of Am.*, 2018 WL 5801056, at *2 (S.D.N.Y. Nov. 6, 2018). "Information is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." *N. Shore-Long Island Jewish Health Sys., Inc. v. MultiPlan, Inc.*, 325 F.R.D. 36, 47 (E.D.N.Y. 2018). "Once relevance has been shown, it is up to the responding party to justify curtailing discovery." *Fireman's Fund Ins. Co. v. Great Am. Ins. Co. of New York*, 284 F.R.D. 132, 135 (S.D.N.Y. 2012).

B. The Requested Data Showing Defendants' Branded and Generic Exforge Sales Through December 2017 Is Relevant

Defendants dispute that their post-2015 branded and generic Exforge sales data is relevant to damages, and have refused to produce 2016-2017 sales data.[4] Defendants' 2016-2017 data is relevant to Plaintiffs' damages calculations, however. Par launched generic Exforge on September 30, 2014 pursuant to its agreement with Novartis, which Plaintiffs allege delayed Par's generic entry.[5] Under Defendants' proposal to produce data only through 2015, Plaintiffs would obtain data showing only 15 months of sales following generic entry (from October 2014 through December 2015). Plaintiffs' damages, however, likely continued for *years* after generic Exforge finally launched, past 2015, and thus Defendants' 2016-2017 sales data is relevant.

Dr. Leitzinger, who has substantial experience analyzing the anticompetitive effects of delayed competition in similar pharmaceutical antitrust cases, and whose damages calculations have been repeatedly accepted by courts in these matters,[6] explains the relevance of the

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[4] Antitrust cases are data-intensive and require substantial data analysis. *See* F. Matthew Ralph & Caroline B. Sweeney, E-Discovery and Antitrust Litigation, 26 ANTITRUST 58, 61 (2011) ("production of voluminous transactional data . . . in an antitrust case is routine and happens in every case.") (internal marks and citation omitted); *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 632 (1985) ("antitrust issues, prone to complication, require sophisticated legal and economic analysis"). Denying necessary data discovery can constitute reversible error. *See, e.g., Valley Drug Co. v. Geneva Pharm., Inc.*, 350 F.3d 1181, 1192 (11th Cir. 2003) (vacating antitrust decision for failure to allow appropriate data discovery).

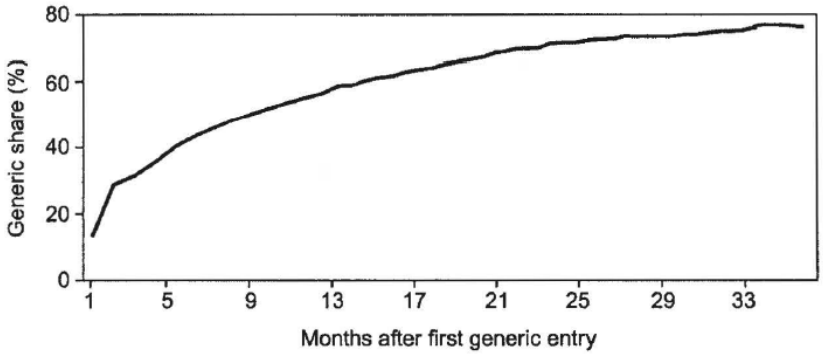
[5] ECF No. 47, Consolidated Amended Class Action Complaint, filed by the Direct Purchaser Plaintiffs on July 18, 2018, at ¶¶ 6, 151. The other complaints include similar allegations.

[6] *See* Ex. A, Leitzinger Affidavit, at Ex. 1, ¶¶ 1, 3 & n.4; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777, at *8-10 (D. Mass. Oct. 16, 2017); *In re Lidoderm Antitrust Litig.*, 2017 WL 679367, at *10-12 (N.D. Cal. Feb. 21, 2017); *In re Prograf Antitrust Litig.*, 2013 WL 2395083, at *3 (D. Mass. Apr. 23, 2013); *In re Wellbutrin XL Antitrust*

requested data through 2017 in his affidavit:

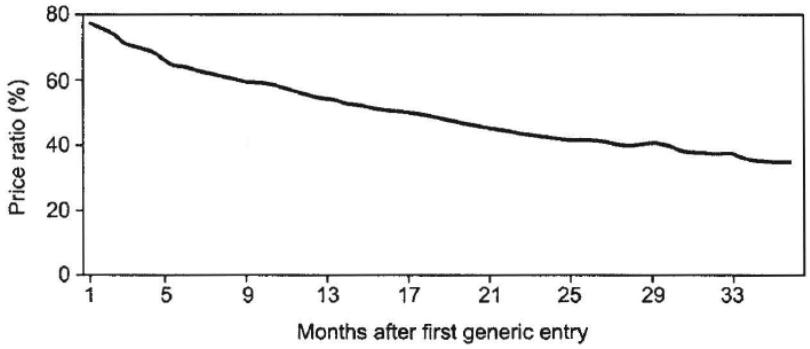
> As a reflection of the literature and my past experience summarized above, overcharges resulting from the delay in generic entry alleged in this case easily could last for years following the actual period of generic delay. Of course, one doesn't know how long the overcharges persisted in this case (assuming the existence of the delay alleged by Plaintiffs) until undertaking the overcharge analysis, but given what we do know about the likely prospect of continuing overcharge, data from Defendants regarding prices and volumes associated with sales of Exforge and its generics through 2017 will almost certainly be relevant.[7]

Dr. Leitzinger's opinion is well-supported by substantial economic literature showing that prices typically continue to fall for years following generic entry, additional evidence confirming that Plaintiffs likely suffered damages for more than 15 months following generic entry. Ex. A, Leitzinger Affidavit, at ¶¶ 6-9. For example, Dr. Leitzinger cites literature showing that the price discounts caused by generic competition continue to increase for up to *five years* after generic entry. *Id.* at ¶¶ 8-9. Dr. Leitzinger's affidavit also includes two charts from a published academic article showing that the generic's share of the market continues to increase and generic prices continue to fall for *at least* 33 months after generic entry:



Litig., 2011 WL 3563385, at *15 (E.D. Pa. Aug. 11, 2011); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 229-31 (D. Del. 2008); *In re K-Dur Antitrust Litig.*, 2008 WL 2699390, at *18-19 (D.N.J. 2008), *aff'd*, 686 F.3d 197 (3d Cir. 2012); *In re Nifedipine Antitrust Litig.*, 246 F.R.D. 365, 370-71 (D.D.C. 2007); *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2008 WL 11399716, at *3 (S.D.N.Y. Apr. 8, 2008); *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 309-12 (D.D.C. 2007); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 344-45 (D. Mass. 2003).

[7] Ex. A, Leitzinger Affidavit, at ¶ 11.



Id. at ¶¶ 8, 9 (citing Saha, A. *et al*., "Generic Competition in the US Pharmaceutical Industry," INT'L J. OF THE ECON. OF BUS., n. 1, v. 13 (Feb. 2006)). This literature shows that prices fall over time, regardless of the number of generic competitors. Thus, Defendants' claim (even if true) that generic prices are not necessarily incrementally lower with additional generics over and above four or five generic competitors (Defendants' Position, § D, *infra*) is irrelevant because Plaintiffs *are not* claiming that the prices fell after 2015 because additional generic competitors launched after 2015. Rather, prices likely continued to fall and Plaintiffs' damages likely continued past 2015 because, regardless of the number of generic competitors, lower-priced generics typically continue to gain sales from the branded and *generic prices continue to fall for years after generic entry*.

Plaintiffs' allegations that generic entry, in general, causes substantial price drops are consistent with this economic literature. *Cf. id.*, § A, *infra*. Plaintiffs have *not* alleged that the full savings associated with generic entry occurred instantaneously, and, indeed, any such claim is refuted by the economic literature. In addition, Defendants' reliance on the Court's recent order regarding the time period for Defendants' production of discovery relevant to computing the value of a no-AG agreement is misplaced. *Id.*, § A, *infra*. The Court's prior order does not relate to the time period for which Plaintiffs suffered damages, and thus has no bearing on this motion. ECF No. 165 at 2.

Dr. Leitzinger's considerable experience calculating damages in nearly identical generic suppression cases confirms that damages from delayed generic competition routinely extend for longer than 15 months following generic entry. Ex. A, Leitzinger Affidavit, at ¶¶ 3, 5 & n.5. For example, Dr. Leitzinger calculated damages in the *Solodyn* litigation continuing for four years following generic entry; in *Wellbutrin XL*,[8] Dr. Leitzinger found that damages lasting for

[8] Defendants suggest that Dr. Leitzinger's *Wellbutrin XL* damages calculations were criticized or excluded under *Daubert* (Defendants' Position, § D), but the footnote Defendants quote makes clear that the *Daubert* challenge against Dr. Leitzinger related to his rule of reason analysis, not to his class certification analysis or damages calculations. *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 757 & n.36 (E.D. Pa. 2015) ("GSK has filed a *Daubert* motion to exclude Dr. Leitzinger's ***testimony regarding a rule of reason*** analysis of the Wellbutrin Settlement on the grounds that Leitzinger has rested his analysis exclusively on counsel's instructions rather than an independent analysis of the summary judgment record. . . .") (emphasis added). In fact, the *Wellbutrin XL* court credited Dr. Leitzinger's damages calculation in certifying the class of direct purchasers and in approving the plan of allocation to the direct purchaser class. *Wellbutrin*

more than 2.5 years after generic entry; and, in *Prograf*, Dr. Leitzinger concluded that the direct purchaser class's damages continued for nearly two and a half years after generic entry. Ex. A, Leitzinger Affidavit, at ¶ 10 & nn. 10-13 (citing public filings); *Solodyn*, 2017 WL 4621777, at *1, *9-10 (damages ran for years after multiple generics launched in 2011).[9]

The caselaw provides no support for Defendants' attempt to arbitrarily limit the time period for their sales data production. Courts routinely reject efforts to block discovery of relevant information from time periods that pre-date or post-date the time period in which the anticompetitive conduct occurred. *See, e.g.*, *Arrowpac Inc. v. Sea Star Line, LLC*, 2014 WL 12617575, at *3 (M.D. Fla. Sept. 11, 2014) (rejecting argument that post-conspiracy documents were irrelevant and ordering production of documents); *Kleen Prods. LLC v. Packaging Corp. of Am.*, 2013 WL 120240, at *9 (N.D. Ill. Jan. 9, 2013) (granting plaintiffs' motion to compel the production of pre- and post- class period documents and transactional data in light of the "expansive view of discovery in antitrust cases" and "defendants' lack of demonstration of burden"); *B-S Steel of Kansas, Inc. v. Texas Indus., Inc.*, 2003 WL 21939019, at *3 (D. Kan. 2003) ("courts [have] held that the temporal scope of discovery in antitrust cases should not be confined to the limitations period of the antitrust statutes or the damage period, and plaintiff is ordinarily permitted to discover defendant's activities for a reasonable period of time antedating the earliest possible date of the actionable wrong"); *In re Shopping Carts Antitrust Litig.*, 95 F.R.D. 299, 309 (S.D.N.Y. 1982) (finding that production post-conspiracy sales data would "provide plaintiffs with information relevant to damages. Plaintiffs are entitled to obtain such information . . . ."); *In re Folding Carton Antitrust Litig.*, 83 F.R.D. 251, 254 (N.D. Ill. 1978) (allowing discovery after conspiracy period because such information was relevant to damages); *Maritime Cinema Serv. Corp. v. Movies En Route, Inc.*, 60 F.R.D. 587, 591 (S.D.N.Y. 1973) (noting that "discovery under the Federal Rules, particularly in antitrust cases, is extremely broad," that "discovery in antitrust cases routinely goes beyond the damage period," and ordering production of information). *See also Lightsquared Inc. v. Deere & Co.*, 2015 WL 8675377, at *4 (S.D.N.Y. Dec. 10, 2015) (Francis, M.J.) (permitting a broader discovery time period where plaintiff "sufficiently established the potential relevance of the disputed period even though that time-frame post-dates the defendants' alleged [acts giving rise to liability]"); *In re Chocolate Confectionary Antitrust Litig.*, 2013 WL 11305184, at *9 (M.D. Pa. May 10, 2013) (finding expert's damages calculation that included damages beyond conspiracy period to be "reasonable"); *In re Natural Gas Commodities Litig.*, 235 F.R.D. 241, 247 (S.D.N.Y. 2006) (in commodities manipulation case, on the basis of submitted expert reports, court granted motion to compel broad production of trade data for locations not at center of alleged wrongdoing because "published price indices for trades at locations other than the Henry Hub are closely correlated and related to prices of NYMEX natural gas futures contracts").

XL, 2011 WL 3563385, at *14-16 (certifying the class and finding predominance met as to damages based on Dr. Leitzinger's damages calculations); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431 (E.D. Pa.), ECF No. 485, at ¶ 9 (approving the plan of distribution, which "proposes to distribute the net settlement proceeds *pro rata* based on class members' purchases of Wellbutrin XL during the class period").

[9] Dr. Leitzinger's affidavit, like Plaintiffs' portion of this joint letter, cites to and relies upon public information about similar pharmaceutical antitrust cases that is equally available to Defendants and Plaintiffs.

Indeed, in the *Generic Pharmaceuticals Pricing Antitrust Litigation*, defendants were ordered to produce data covering at least two full calendar years before the challenged conduct began through the end of 2018, more than two-and-a-half years after the first complaints were filed. *See* Exhibit B, Special Discovery Master's April 3, 2019 Letter, *In re Generic Pharms. Pricing Antitrust Litig.*, MDL No. 2724 (E.D. Pa. Jan. 8, 2019), at p.2, § 1.B; Exhibit C, *In re Generic Pharms. Pricing Antitrust Litig.*, MDL No. 2724 (E.D. Pa.), Pretrial Order No. 82, ECF No. 930 (adopting the Special Discovery Master's April 3, 2019 Letter).

Defendants' claim that the *class period* in other pharmaceutical antitrust cases does not uniformly run for years after generic entry (Defendants' Position, § D, *infra*) misses the point. Damages do not necessarily cease at the end of the class period; the class period determines class membership, not the damages period. Damages routinely continue after the end of the class period, including in the cases Defendants cite.[10] For example, in *In re Namenda Direct Purchaser Antitrust Litigation*, the Southern District of New York certified a class of direct purchasers where the class period ran from June 2012 through September 2015, based on plaintiffs' expert's damages calculation showing that damages continued through June 2017, nearly two years after the end of the class period and twenty-three months after generic entry occurred in July 2015.[11] Defendants' 2016-2017 sales data is relevant because Plaintiffs' damages likely continued past 2015, regardless of the end date for the class period.

Finally, Defendants' claim that Plaintiffs already possess adequate 2016-2017 data is incorrect. *Cf.* Defendants' Position, § C, *infra*. Plaintiffs possess data showing 2016-2017 purchases of branded and generic Exforge made *by the named plaintiffs*. However, Plaintiffs do not possess data showing the 2016-2017 branded and generic Exforge purchases made by *absent members* of the Direct Purchaser Plaintiff Class and the End-Payor Plaintiff Class. The named plaintiffs' data is no substitute for Defendants' 2016-2017 marketwide sales data showing

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[10] In *Lidoderm*, the class period ran through May 1, 2014 but damages ran longer, through March 16, 2015. 2017 WL 679367, at *3, *9 n.13 (certifying a class of direct purchasers with a class period ending on May 1, 2014, and noting that generic entry occurred on September 15, 2013); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521 (N.D. Cal.), ECF No. 1004-6, Declaration of Jeffrey J. Leitzinger, Ph.D. Related to Proposed Allocation Plan and Net Settlement Fund Allocation, at ¶ 3 (damages ran through March 16, 2015); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521 (N.D. Cal.), ECF No. 1004-5, Direct Purchaser Plaintiffs' Proposed Plan of Allocation for the Direct Purchaser Class, at ¶ 2.1 (proposing allocation based on class members' purchases through March 16, 2015); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521 (N.D. Cal.), ECF No. 1054, Order Granting Final Approval of Settlement with Direct Purchaser Class and Entering Final Judgment of Dismissal with Prejudice, at ¶ 9 (approving the plan of allocation).

[11] 331 F. Supp. 3d 152, 205, 215-20 (S.D.N.Y. 2018) (certifying a class of direct purchasers from June 2012 through September 2015 and finding predominance met as to damages based on Dr. Lamb's damages calculations); *id.* at 177-82 (denying motion to exclude Dr. Lamb's opinions and damages calculations); *In re Namenda Direct Purchaser Antitrust Litig.*, No. 1:15-cv-07488-CM-RWL (S.D.N.Y.), Amended Expert Report of Dr. Russell L. Lamb, ECF No. 680-50, at ¶¶ 125-126 (Dr. Lamb calculated aggregate class damages through June 2017); *id.* ¶¶ 9, 62-63 (generic entry occurred in July 2015).

purchases made by all class members. Marketwide sales data is relevant to Plaintiffs' calculation of aggregate class damages, which is the appropriate measure of damages. *See, e.g.*, *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1050 (2016) (approving aggregate damages award); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 534-35 (6th Cir. 2008) (approving use of classwide aggregate damages model); *In re Air Cargo Shipping Servs. Antitrust Litig.*, 2014 WL 7882100, at *61 (E.D.N.Y. Oct. 15, 2014) ("The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself.") (citation omitted); *Lidoderm*, 2017 WL 679367, at *1, *9 (certifying class of direct purchasers where the plaintiffs' "experts have shown how to determine aggregate damages"); *Namenda*, 331 F. Supp. 3d at 177, 217 (similar). Contrary to Defendants' claims, it is not possible to use the named plaintiffs' data to show that aggregate class damages continued after 2015 because, again, such an analysis requires analysis of marketwide data.

C. Production of Sales Data Through December 2017 Would Not Be Unduly Burdensome

Given the relevance of the 2016-2017 data, to block the discovery, Defendants "must show . . . [Plaintiffs' request] is overly broad, burdensome or oppressive by submitting affidavits or offering evidence revealing the nature of the burden." *Sokol v. Wyeth, Inc.*, 2008 WL 3166662, at *3 (S.D.N.Y. Aug. 4, 2008) (internal quotations and modifications omitted). Defendants make no burden argument here. Nor could they. Defendants have agreed to produce their data through 2015 and there is no additional burden to producing data through 2017 as opposed to through 2015. The process for pulling and producing data through 2017 instead of through 2015 will be exactly the same; the only change will be that the data files Defendants produce will be slightly larger. There is thus no burden—let alone undue burden—to producing the relevant 2016-2017 sales data. *See In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4700367, at *3 (S.D.N.Y. Oct. 19, 2017) (granting motion to compel production of non-party generic manufacturer's sales data over manufacturer's "unpersuasive" burden argument).

Defendants' Position

Plaintiffs' efforts to compel production of Defendants' data after December 31, 2015 should be denied for five reasons. First, by Plaintiffs' own allegations, data after 2015 is not relevant to any of their claims. Because Plaintiffs have affirmatively alleged that seven generic competitors entered the market by March 2015, resulting in "intense" price competition, *e.g.*, EPP CAC (1:18-cv-05603, ECF No. 40) ¶¶ 135, 143, 149, data after that date has no bearing on their alleged damages. Second, even if there were overcharges that continued for a limited period beyond the entry of numerous generics, Defendants have already offered to produce an additional ***nine months*** of data—until December 31, 2015. Third, additional discovery is unnecessary because Plaintiffs already possess their own purchasing data (which would show post-2015 changes in prices they paid and any purported overcharges). Fourth, although the Court need not reach Plaintiffs' economic argument, to the extent that the Court wishes to consider the affidavit of Dr. Jeffrey Leitzinger ("Leitzinger Affidavit"), it need not credit it. The cited studies and prior reports by Dr. Leitzinger are either inapposite or actually support Defendants' position. Finally, the burden on Defendants is immaterial because the data is not relevant. For these reasons, Defendants respectfully request that the Court deny Plaintiffs' request for Defendants' 2016-2017 data.

A. Plaintiffs' Allegations of "Intense" Generic Competition in March 2015 Demonstrate the Requested Data Is Not Relevant

Based on Plaintiffs' own allegations, the data Plaintiffs seek has no relevance to their claims in this case. Plaintiffs' sole argument for the relevance of 2016-2017 data is that it relates to damages. However, Plaintiffs admit that seven generic competitors were on the market by March 2015, *see, e.g.*, DPP CAC (1:18-cv-04361, ECF No. 47) ¶ 151, and acknowledge that widespread generic entry yields swift price declines. For example, Plaintiffs allege that earlier generic competition "would have forced decreases in the prices of Exforge" and that "price competition among the suppliers of branded and generic versions of Exforge would have been intense." EPP CAC ¶ 149. Plaintiffs similarly allege that "generic entry leads to ***rapid*** erosion of [] brand sales," *id.* ¶ 37 (emphasis added), and that "[o]nce the second wave of generic competitors enter the market . . . the competitive process ***accelerates***, multiple generic manufacturers compete ***vigorously*** with each other over price, and the price of generics is driven down toward marginal manufacturing costs," *id.* ¶ 40 (emphasis added); *see also* DPP CAC ¶¶ 58, 61 (similar allegations).

Accordingly, as this Court has recognized, Plaintiffs are foreclosed from claiming that the effects of Defendants' purportedly anticompetitive conduct lingered for ***years*** after generic entry. Specifically, in previously "holding that there is no continuing violation after March of 2015", March 27, 2019 Tr. at 36:13-14, the Court noted that "competition with the other entrants would bring [the price] down" and that "[t]he nature of price competition is that it is prompt," *id.* at 34:21-22, 35:17-19. In short, Plaintiffs have pleaded themselves out of any claim to "overcharge" damages after multiple generics entered the market in March 2015. Therefore, 2016-2017 data is not relevant.

The Court followed this approach in its recent ruling on another motion to compel brought by Plaintiffs. When addressing the relevant timeframe for data production related to Novartis's other authorized generics, the Court observed that the "complaint alleges that many manufacturers entered the market on March 30, 2015." ECF No. 165 at 2. The Court then held that "[a]n appropriate temporal scope for the sales data production is the approximately five-year period between January 1, 2010 and March 31, 2015." *Id.* There is no reason the Court should depart from that approach—guided by Plaintiffs' own pleadings—on this motion.

B. Defendants Have Already Agreed To Produce Data For Nine Months After "Intense" Generic Competition

Although Plaintiffs allege the existence of robust generic competition by March 2015, Defendants have nonetheless agreed to produce data through December 31, 2015. Plaintiffs' argument that "[c]ourts routinely reject efforts to block discovery of relevant information from time periods that pre-date or post-date the time period in which the anticompetitive conduct occurred," *supra* at 5, simply ignores that Defendants have *already* agreed to produce data and other relevant information for an additional ***nine months*** after the alleged anticompetitive conduct ceased.

C. Plaintiffs Already Have Post-2015 Pricing Data

Requiring Defendants to produce additional information is unnecessary because Plaintiffs, as customers of Defendants and other generic manufacturers of Exforge, already have in their possession data reflecting their purchases (and, thus, Defendants' sales) of branded and generic Exforge. Such data is sufficient to show whether, under Plaintiffs' theories, any purported "overcharges" occurred after March 2015.

Plaintiffs argue that even if they have enough data regarding their own purchases, they do not have data regarding absent members of the putative classes and that such data is relevant to "class damages." *Supra* at 6–7. Plaintiffs are putting the cart before the horse. Despite having their own purchase data (through not only 2017, but all the way through the present), Plaintiffs have not alleged any facts supporting any damages after March 2015—not in the original complaints, and not in their amended complaints. That Plaintiffs now submit an affidavit relying on literature and other cases, rather than their own data, further demonstrates the absence of such damages. Having failed to plead sufficient facts to allege post-2015 damages using the data already in their possession, Plaintiffs have no basis to compel Defendants to produce this irrelevant data.

D. Plaintiffs' Economic Argument Is Not Persuasive

As an initial matter, Plaintiffs' economic argument cannot be squared with the allegations that Plaintiffs have pled in their respective complaints. In any event, the Leitzinger Affidavit and the literature he cites do not support Plaintiffs' position. Indeed, rather than "confirming that Plaintiffs likely suffered damages for more than 15 months following generic entry", *supra* at 3, the three sources on which Dr. Leitzinger relies each demonstrate just the *opposite*—that once seven competitors had entered the market in March 2015, as Plaintiffs have pled here, there is no viable claim for "overcharge" damages. The Court should not credit the Affidavit.

The first study to which Dr. Leitzinger cites[12] finds that there is no meaningful additional price reduction from generic entry beyond four or five competitors. Berndt, *et al.*, at 798 ("Our analysis of recent data demonstrates that additional generic entrants after the first four or five do not appear to significantly affect long-run generic-to-brand price ratios").[13] Similarly, the Saha,

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[12] Berndt, *et al.*, *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, 26 HEALTH AFFAIRS 790 (2007), *available at* https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.3.790 ("Berndt, *et al.*"). Dr. Leitzinger asserts that Berndt, *et al.*, "reports that the discounts provided by generics relative to brand price are continuing to grow two years after the date of initial generic entry", Ex. A at ¶ 6, but the authors make no such claim. The exhibits to which Dr. Leitzinger cites, *see* Ex. A at ¶ 6 & n.5, are used by the authors not for the proposition Dr. Leitzinger suggests, but rather to support their finding that "high generic penetration and low generic-to-brand price ratios are achieved in the long run, regardless of whether successful paragraph IV certifications occurred." Berndt, *et al.*, at 796.

[13] *See also id.* at 792 ("A sizeable literature considers generic entry . . . [and] suggests that after the first few entrants, the marginal effect of each entrant on generic prices and shares tends to be negligible.")

et al., article[14] on which Dr. Leitzinger relies does not model the separate impact of time on generic prices or shares, but rather assesses the "interactions between generic entry, prices and market shares", ultimately concluding that "the number of generic entrants [is] a key determinant of the level of generics' share and generic-to-brand price ratio." Saha, *et al.*, at 34-35. In other words, prices are a function of not just time, but of the *number of competitors*. Dr. Leitzinger has recently stated as much, relying on this very article.[15] And although Plaintiffs rely on Saha, *et al.*, to argue that "*generic prices continue to fall for years after generic entry*", *supra* at 4, that study focuses on a "sample of drugs that experienced generic competition between July 1992 and January 1998", more than two decades ago. Saha, *et al.*, at 18.[16] As the final source cited by Dr. Leitzinger, the 2016 IMS Study[17], makes clear, more recent generic entries have had "steeper and faster price reductions that earlier cohorts." IMS Study at 4. Specifically, the IMS study surveys generic entries between 2002 and 2014, finding that "[n]early all reductions in price now occur in the first *eight months* after generic entry." IMS Study at 4 (emphasis added). The study also found that "[p]rice reductions occur faster for oral medicines" (such as Exforge), relative to "injectable drugs, which often attract fewer generic competitors". *Id.* at 3. Thus, the literature on which Dr. Leitzinger and Plaintiffs rely shows that the number of generic competitors is a key determinant of price, that the effect on price from entry beyond four or five competitors is negligible, and that nearly all price reductions now occur in a matter of months from generic entry. Plaintiffs here allege that, by March 2015, seven generic competitors for Exforge had entered the market—data post-dating December 2015, more than nine months later, accordingly has no relevance to Plaintiffs' alleged damages.

Plaintiffs also identify three examples of Dr. Leitzinger's calculations from prior cases in an effort to bolster their argument that "damages from delayed generic competition routinely extend for longer than 15 months following generic entry," *supra* at 4, but these examples similarly fail to withstand scrutiny. For instance, Plaintiffs cite to *In re Wellbutrin XL* for the proposition that Dr. Leitzinger found damages lasting "for more than 2.5 years after generic entry", *supra* at 4-5, but fail to disclose that plaintiffs in that case alleged delayed generic entry for two dosage strengths of the product at issue, which occurred in 2006 and 2008, respectively, and the "2.5 years after generic entry" was calculated from 2006, not 2008. *See In re Wellbutrin*

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[14] Saha, et al., *Generic Competition in the US Pharmaceutical Industry*, 13 INT'L J. OF THE ECON. OF BUS. (2006), *available at* https://pdfs.semanticscholar.org/c828/4f078c063ed7fc963ea67f6e85421bc3d811.pdf ("Saha, *et al.*").

[15] [Redacted] Expert Report of Jeffrey J. Leitzinger, Ph.D. at ¶ 21 & n.33, *In re Celebrex (Celecoxib) Antitrust Litig.*, No. 2:14-cv-00361, ECF No. 195 (E.D. Va. April 5, 2017) ("Celebrex Report") ("The literature also shows that the pricing benefits created by generic competition increase with the number of competitors") (citing Saha, *et al.*)).

[16] Similarly, Berndt, et al., studies data on generic entry from 1999 through 2003. Berndt, *et al.*, at 790.

[17] IMS Institute for Healthcare Informatics, Price Declines after Branded Medicines Lose Exclusivity in the U.S. (January 2016), *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf ("IMS Study").

XL Antitrust Litig., No. 08-2431, 2011 WL 3563385, at *4 (E.D. Pa. Aug. 11, 2011) ("[P]laintiff contends that [defendants'] scheme caused [one generic dosage strength] to enter the market in December, 2006 . . . and . . . prevented entry of [a second generic dosage strength] until May, 2008."). Notably, the court in *Wellbutrin* ultimately granted summary judgment in favor of the defendant, expressly finding that "Dr. Leitzinger's analysis of the Wellbutrin Settlement's effects are unreliable under *Daubert* and are excluded." 133 F. Supp. 3d 734, 757 & n.36 (E.D. Pa. 2015).

Similarly, in asserting that "Dr. Leitzinger calculated damages in the *Solodyn* litigation continuing for four years after generic entry," *supra* at 4, Plaintiffs fail to mention that the "four years" was calculated based on dosage strengths of the relevant drug for which generic entry had not occurred as of the filing of the complaint. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777, at *1 (D. Mass. Oct. 16, 2017) (discussing launch of "generic Legacy Strength Solodyn in November 2011" and "delay[ed] launch of generic Add-On Strength Solodyn until at least February 2018"); *id.* at *3, *11 (including in class definitions purchasers of both Legacy Strength and Add-On Strength Solodyn). That is, plaintiffs in *Solodyn* alleged damages from delayed generic entry of multiple dosage strengths of the relevant product that had not yet occurred. Here, however, Plaintiffs allege that generic entry of all four Exforge dosage strengths occurred in September 2014, and that multiple competitors were on the market by March 2015.

Nor does *In re Prograf* support Plaintiffs' position. There—unlike this case—it took ***years*** for multiple generic competitors to enter the market and reduce prices. *See* [Redacted] Declaration of Jeffrey J. Leitzinger, Ph.D. at ¶ 24, *In re Prograf Antitrust Litig.*, No. 11-md-02242-RWZ, ECF No. 171 (February 13, 2013) ("During the period 2009 through mid-2012, six pharmaceutical manufacturers began selling generic [versions of the product at issue]"). Here, by contrast, Plaintiffs affirmatively plead that by March 2015 there were at least seven generic versions of Exforge on the market, *see, e.g.*, DPP CAC ¶ 151, the result of which was "intense" price competition. EPP CAC ¶ 149.

Aside from the examples that Plaintiffs have selectively highlighted, Dr. Leitzinger has conducted economic analyses of damages in numerous other cases. *See* Ex. A at ¶ 3 & n.4. Although many of those analyses have been filed under seal or redacted,[18] what is evident from information that *is* publicly available is that plaintiffs' proposed class period in those cases routinely extended only to (at most) ***months*** past the date of generic entry. *See, e.g.*, Celebrex Report at ¶ 6, n.3 and ¶ 18, (class period running approximately three months after five generics entered the market); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2017 WL 679367, at *3 (N.D. Cal. Feb. 21, 2017) (direct purchaser class period ending at launch of authorized generic and end-payor class period ending three months thereafter); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 309 F.R.D. 195, 201-202 (E.D. Pa. 2015), *vacated and remanded by In re Modafinil Antitrust Litig.*, 837 F. 3d 238 (3d Cir. 2016) (class period running approximately four months after generic entry); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 WL 2699390, at *1

[18] To the extent Plaintiffs seek to rely on these analyses, Defendants have no means of fully assessing the claims contained therein. Defendants have no access to the data underlying Dr. Leitzinger's findings, nor do Defendants have unsealed or unredacted copies of the vast majority of the reports to which Plaintiffs cite.

(D.N.J. Apr. 14, 2008) (class period running less than one month after generic entry); *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, 246 F.R.D. 293, 300 & n.5 (D.D.C. 2007) (class period running approximately two months after generic entry). Here, Defendants' agreement to produce data for 15 months following the initial generic entry date, and for nine months following the entry of numerous generic competitors, is more than sufficient.

Although Plaintiffs argue that "[d]amages do not *necessarily*" cease at the end of the class period, *supra at* 6 (emphasis added), the cases they cite do not lend support to their assertion. Specifically, Plaintiffs argue that the class period and damages period that plaintiffs argued for in *Lidoderm* were not identical. *Supra* at 6, n.10. But *Lidoderm* ended in a settlement, and there was no ruling by the Court on the merits of this argument. How the plaintiffs chose to allocate the settlement fund is irrelevant. Similarly, Plaintiffs rely on an expert report, not a court ruling, for their argument that the class period and damages period were different in *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018), *supra* at 6 & n.11. Notwithstanding Plaintiffs' characterization of the case, *supra* at 6, the court in *Namenda* made no finding that damages through 2017 were proper. And again, in this case, Plaintiffs have not even pled a theory that would seek such a finding.

Plaintiffs' reliance on case law is similarly unpersuasive. Beyond the cases cited in the Leitzinger Affidavit, Plaintiffs rely almost exclusively on cases outside the pharmaceutical industry which are inapposite. Specifically, Plaintiffs cite only a single pharmaceutical case, *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, arguing that "defendants were ordered to produce data . . . through the end of 2018, more than two-and-a-half years after the first complaints were filed." *Supra* at 5-6. But that case deals with allegations of ongoing anticompetitive conduct and therefore post-filing data had at least some connection to the claims at issue. *See* DPP Am. Compl. at ¶ 493, *In re Generic Pharms. Pricing Antitrust Litig*., No. 2:18-cv-02641-CMR, ECF No. 11 (E.D. Pa. Dec. 21, 2018) ("Defendants' anticompetitive conduct is ongoing."). No such ongoing misconduct is alleged here; rather, any alleged misconduct ceased in March 2015, more than three years before the first complaint, when seven generics were actively competing in the market.

E. The Burden on Defendants Is Immaterial

Plaintiffs argue that the production of sales data through December 2017 is not unduly burdensome. *Supra* at 7. But Rule 26 makes clear that discovery is only permitted when the material "is relevant to any party's claim or defense ***and*** proportional to the needs of the case". Fed. R. Civ. P. 26(b)(1) (emphasis added). Therefore, Plaintiffs cannot obtain discovery that is not relevant, regardless of the burden it imposes. Because, for the reasons set forth above, the requested data does not satisfy the initial requirement of relevance, the burden on Defendants is immaterial.

For the foregoing reasons, Defendants respectfully submit that this Court should deny Plaintiffs' request for Defendants' 2016-2017 data.

Sincerely,

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